Dutch Parkinson, Cognition and Driving Ability study (DUPARC-drive): An explorative study on driving simulator performance in de novo Parkinson's Disease patients.

Published: 03-08-2020
Last updated: 13-01-2025

The primary objective of this study is to study whether driving ability may be affected in de novo, treatment naïve PD patients, by comparing their driving simulator performance to age- and sex-matched healthy controls (HC). The secondary objective...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON49421

Source
ToetsingOnline

Brief title
Driving ability in de novo Parkinson's Disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognition, Driving ability, Driving simulator, Parkinson's Disease

Outcome measures

Primary outcome

The primary endpoint will be driving simulator performance of de novo PD patients compared to HC, using the standard deviation of the lateral position (SDLP) during Swing Drive part 1 as primary variable.

Secondary outcome

Secondary endpoints will be other driving simulator variables (e.g. speed, percentage of lane crossing, reaction time to triggered events and number of violations) and the identification of correlates between SDLP and potential predictors, i.e. neuropsychological test scores and motor scores.

Study description

Background summary

Parkinson*s disease (PD) is a complex neurodegenerative disease, with cognitive impairment being one of the most important non-motor symptoms. Cognitive decline can impair the execution of many complex tasks in daily activities, for example driving a car. It is established that driving ability is diminished in PD patients in which a decline in cognitive functioning is an important factor. However, cognitive decline can also precede motor manifestations of PD by years, suggesting that recently diagnosed de novo PD patients might already be at risk for unsafe driving. The proposed study will be the first study to explore driving ability in de novo, treatment-naïve PD patients.

Study objective

The primary objective of this study is to study whether driving ability may be affected in de novo, treatment naïve PD patients, by comparing their driving simulator performance to age- and sex-matched healthy controls (HC). The secondary objective is to explore neuropsychological- and motor variables that may correlate with driving simulator performance at time of diagnosis.

Study design

This study is designed as an explorative study of 30 de novo PD patients and 30 sex- and age matched healthy controls (HC), all currently active drivers. Patients and HC will undergo neuropsychological assessment and driving simulator assessment.

Study burden and risks

There are no direct benefits for the patient. A potential risk is simulator sickness (similar to car sickness) during the driving simulator test. Participants are notified of this possibility beforehand and will be monitored during the test. They will also be informed of their right to stop the test at any time. A general risk is that assessments (neuropsychological assessment and driving simulator assessment) can be too demanding for patients; however, neuropsychologists carrying out the assessments are experienced in testing vulnerable patients and will carefully check whether the assessments are too demanding, and quit if necessary. Performance on any of the assessments does not have legal consequences for the participant*s fitness to drive.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All subjects:
- Dutch speaking
- In possession of a driver's license
- Active driver, i.e. having driven at least 300 kilometres in the last year
- Age 18 to 75 (participants aged 75 years or over will be excluded)
- Willingness to cooperate and sign written informed consent

Patients:
- diagnosis of Parkinson's disease
- disease duration <3 months, measured after time of diagnosis

Exclusion criteria

All subjects:
- Suffering from severe motion sickness (risk factor for simulator sickness)
- Use of category III medication

Patients:
- History of dopaminergic medication use
- Presence of premorbid pathology, i.e. experienced cerebral infarction or chronic depression, non-related to Parkinson's disease.

Healthy controls:
- History of neurological disorders, which may interfere with cognitive functioning (e.g. recent concussion, previous subarachnoid or intracerebral haemorrhage, intracranial tumours, epilepsy, ischemic strokes).
- Presence of psychiatric disorders, i.e. depression or psychosis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	03-08-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20215
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	In afwachting
CCMO	NL73666.042.20
OMON	NL-OMON20215